

K122987

OCT 25 2012

## **Section. 6      510(k) Summary**

Company Name:      Cardiovascular Systems, Inc.  
651 Campus Drive  
Saint Paul, MN 55112

Contact:              Maureen McDonnell

Phone:                (651) 259-1644

Fax:                    (651) 305-7734

Summary Date:      September 25, 2012

Trade Name:          Stealth 360°® Orbital PAD System

Common Name:      Peripheral Atherectomy Device

Classification Name: Peripheral Atherectomy Catheter (21 CFR 870.4875; Product Code: MCW)

Predicate Device:

510(k) Number:	K110389
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Stealth 360°® Orbital PAD System

### **6.1      Description of Device**

The Stealth 360° Orbital PAD System is an orbital atherectomy system (OAS) that is intended for use in the treatment of peripheral arteries and A-V graft (shunt) stenosis.

The OAS provides a method of removing stenotic material from peripheral arteries and A-V grafts. The Stealth 360° uses an electrically driven shaft to apply a diamond coated, eccentrically rotating sanding surface to ablate stenotic material. The stenotic particles that are removed are small enough to be absorbed by the body.

The Stealth 360° Orbital PAD System consists of the following components:

- 1) Orbital atherectomy device (OAD)
- 2) Atherectomy guide wire
- 3) Externally operated saline pump
- 4) Atherectomy Lubricant (e.g. ViperSlide)

## **6.2 Intended Use**

The Stealth 360° Orbital PAD System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

## **6.3 Technology**

The Stealth 360° Orbital PAD System provides a method of removing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating sanding surface to ablate stenotic tissue. The stenotic particles that are removed are small enough to be absorbed by the body. This same technology was cleared to market for use in 510(k) K110389, 510(k) K071350, and Predator 360° (originally cleared as 3X) per K090521.

The device crowns are comprised of blanks that are plated and diamond coated. The primary difference between the device that is the subject of this submission and the predicate device is that the current solid crown blanks are machined and the crown blanks for the modified device will be molded. Molding blanks is intended to be another method for producing a crown of the same material composition as the current blank. The plating and diamond coating processes will be exactly the same for both blanks.

## **6.4 Performance Data**

The modified Stealth 360° Orbital PAD System was evaluated using the following performance bench testing to confirm the performance characteristics as compared to the predicate device.

- Life/Stall Testing
- Orbit Testing

## **6.5 Conclusions**

The Stealth 360° Orbital PAD System with the molded crown is substantially equivalent to the predicate device. Design verification testing was performed to support the safety profile of the modified Stealth 360° Orbital PAD System. Testing results demonstrate that the modified Stealth 360° Orbital PAD System is as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

OCT 25 2012

Cardiovascular Systems, Inc.  
c/o Maureen McDonnell  
Senior Regulatory Affairs Specialist  
651 Campus Drive  
St. Paul, MN 55112

Re: K122987

Trade/Device Name: Stealth 360° Orbital PAD System  
Regulation Number: 21 CFR 870.4875  
Regulation Name: Peripheral Atherectomy Catheter  
Regulatory Class: Class II  
Product Code: MCW  
Dated: September 25, 2012  
Received: September 26, 2012

Dear Ms. McDonnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

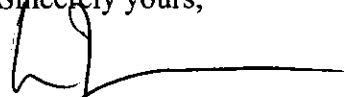
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram Zuckerman', with a long horizontal stroke extending to the right.

Bram Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

## Section. 5      Indications for Use Statement

510(k) Number: K122987

Device Name: Stealth 360°® Orbital PAD System

### Indications for Use:

The Stealth 360° Orbital PAD System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

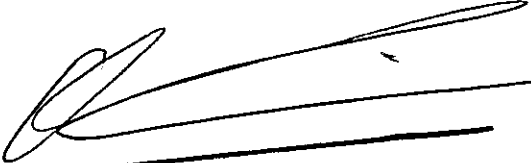
The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR      Over-The-Counter Use \_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K122987